SmartPA Criteria Proposal

Drug/Drug Class:	Electrolyte Depleting Agents, Potassium Lowering PDL Edit
First Implementation Date:	April 4, 2019
Proposed Date:	September 15, 2022
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	☐ Existing Criteria ☒ Revision of Existing Criteria ☐ New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Participants with chronic kidney disease and heart failure are at a higher risk for hyperkalemia, especially in participants who take medications that may increase potassium levels already such as any renin-angiotensin-aldosterone system (RAAS) inhibitor. The main causes of hyperkalemia involve increased potassium release from the cells or decreased urinary potassium excretion. Potassium enters the body exogenously through diet, oral intake, or intravenous infusion, stored in the cells and then excreted in the urine. Without a controlled potassium level, an increase in potassium levels may lead to muscle paralysis and potentially fatal cardiac arrhythmias. Management of chronic hyperkalemia in these participants can include pharmacologic management with a non-absorbable cation exchanger, such as sodium polystyrene sulfonate, patiromer, and sodium zirconium cyclosilicate. Dichlorphenamide, a carbonic anhydrase inhibitor (CAI), is approved for use in participants with primary hypokalemic and hyperkalemic periodic paralysis and related variants. There are no other FDA-approved alternatives for this disease state however, acetazolamide, also a CAI, has been used for treatment of periodic paralysis off-label and should be considered.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:

Preferred Agents	Non-Preferred Agents
• Kionex® Susp • Sodium Polystyrene Sulfonate Pwd/Susp • SPS® Susp • SPS® Rectal Enema • **Veltassa® Pwd Pack**	• Keveyis® • Lokelma®

Type of Criteria:
☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☒ **Preferred Drug List**
☐ **Clinical Edit**

Data Sources:
☐ **Only Administrative Databases**
☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Electrolyte Depleting Agents, Potassium Lowering
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participants aged 18 years or older for non-preferred agents **AND**
- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents **AND**
- ~~For Lokelma: documented therapeutic trial (60 days) of Veltassa in the past year OR~~
- For Keveyis: documented diagnosis of periodic paralysis as determined by at clinical consultant review

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

Required Documentation

Laboratory Results:	☐	Progress Notes:	☐
MedWatch Form:	☐	Other:	☐

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

- Evidence-Based Medicine Analysis: "Electrolyte Depleter, Potassium Lowering Agents", UMKC-DIC; April 2022.
- Mount, D., (2019). Causes and evaluation of hyperkalemia in adults. In J.P. Forman (Ed.), *UpToDate.*
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.